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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 09/924,428   | 08/07/2001  | Lei Wu               | 4718420005000       | 3614             |
| 25225  | 7590        | 03/22/2004           | EXAMINER            |                  |
| MORRISON & FOERSTER LLP<br>3811 VALLEY CENTRE DRIVE<br>SUITE 500<br>SAN DIEGO, CA 92130-2332 |             |                      | CHEU, CHANGHWA J    |                  |
|  |             | ART UNIT             | PAPER NUMBER        |                  |
|  |             | 1641                 |                     |                  |

DATE MAILED: 03/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                        |                     |  |
|------------------------------|------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|                              | 09/924,428             | WU ET AL.           |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                              | Jacob Cheu             | 1641                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 24 December 2003.
- 2a) This action is FINAL.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-14, 16-20, 25-31, 33-34, 56-57, 67-68, 92-93, 95, 115-116 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-14, 16-20, 25-31, 33, 34, 56, 57, 67, 68, 92, 93, 95, 115 and 116 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

|   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)             | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____ .  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ .   | 6) <input type="checkbox"/> Other: _____ .                                  |

### **DETAILED ACTION**

Applicant's amendment filed on 12/29/2003 has been received and entered into record and considered.

The following information provided in the amendment affects the instant application:

1. Claims 15, 21-24, 32 and 94 are cancelled.
2. Claim 116 is added to the instant application.
3. Currently, claims 1-14, 16-20, 25-31, 33, 34, 56, 57, 67, 68, 92, 93, 95, 115 and 116 are under examination.
4. The indication of allowable subject matters in the previous Office Action is hereby withdrawn in view of the newly applied references.

#### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:  
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
2. Claims 1-14, 16-20, 25-31, 33, 34 and 56-57, 68, 92, 93, 95, 115 and 116 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, step (c ), “a binding partner that is capable of binding to a moiety to be manipulated” is vague and indefinite. It is unclear where the said binding partner is located within this microdevice. Similarly, claim 56 shares the same problem.

With respect to 5, line 3, “rectangular parallelepiped (cuboid)” is vague and indefinite. It is unclear whether the “(cuboid)” is an intended limitation.

With respect to claim 116, line 2, “a letter or a structure” is vague and indefinite. It is unclear what is “a structure”.

***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claims 1-2, 5, 116 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chan et al (US 5120662), Tiffany et al. (US 5508200), or Liotta et al. (US 5942407) in view of Dames et al. (WO 00/16893).

The aforementioned prior art, *each individually*, teaches features recited in the instant invention, including a device comprising a substrate, a photorecognizable coding pattern on the substrate (e.g. bar code), a binding partner capable of binding to a moiety to be manipulated and no need of anodized metal surface layer.

For Chan et al. reference, see Figure 11, where the binding layer (component 84) as substrate for binding partner, and photorecognizable bar code (component 94) is on the substrate.

For Tiffany et al. reference, see Figure 2, where component 17 is a substrate which can be bound to binding partners, and component 10 is a photorecognizable bar code (Col. 5, line 25-37).

For Liotta et al. reference, see Figure 1A-1B, where layer 10 is a substrate containing binding partner ligand, and bar code photorecognizable pattern (Figure 5, Col. 15, line 17-25; Col. 17, line 25-30).

However, no feature of “photorecognizable coding pattern comprising a hole not penetrating through the entire of said substrate” is taught by the above Chan, Tiffany, and Liotta et al. references. Nevertheless, Dames et al. teach a micro-label design to identify analyte of interest in a solution. Dames et al. teach using a photorecognizable coding pattern on a substrates, i.e. bar code formed by a series of holes on the metal layer. (See page 3, line 26-29) The device taught by Dames et al. provide a low-cost, fast and convenient manner for identifying purposes through flow cytometry reader system, or fluorescence/imaging microscopy. (See page 2, line 13-15; page 3, line 6-8; claim 14-19) The examiner would like to point out that in combination of Dames et al. teaching, i.e. the photorecognizable bar code having holes on the micro-label device, with the references of Chan, Liotta or Tiffany, the bar code would attach on a substrate not penetrating through the depth of the substrate. (See Figure 11 in Chan et al.; Figure 2 in Tiffany; Figure 5 in Liotta) Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided either the device of Chan, Liotta or Tiffany with the photorecognizable bar code as taught by Dames et al. for low-cost and convenient identifying analyte of interest in a test sample.

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6. Claims 1-6, 11, 16-20, 25-29, 31, 33-34, 56-57, 67-68, 92, 95, 115, 116 are rejected under 35 U.S.C. 102(e) as being unpatentable by Cattell (US 6180351) in view of Dames et al.

Cattell teaches an addressable array of biopolymers, such as DNA probes, on a substrate. (See abstract) The DNA probes are the binding partners which can be manipulated by hybridization binding reaction. The substrates are selected from the group consisting of glass, silicon dioxide (i.e. silica), metals and plastics. (Col. 13, line 65 to Col. 14, line 1-5) Cattell teaches that the substrate surface layer can be modified by adding organic or inorganic layers, and the modified layer thickness can be ranged from 0.1 mm to 1 micron. (Col. 14, line 12-16) The bar code (component 356) is lithographically fabricated on the glass substrate (component 10). (See Figure 1) The bar code substance is deposited on the substrate for photorecognition. (See Figure 1) Cattell also teaches using fluorescent markers for the detection of the binding pattern. (Col. 1, line 22-25) Cattell teaches that the substrate shape may be of any shape. (Col. 7, line 45-46) The device taught by Cattell does not comprise an anodized metal surface layer. With respect to claim 4, the instant claim recites that the surface is either hydrophilic or hydrophobic. Cattell teaches that the surface layer can be modified by either organic or inorganic approaches, therefore would be obvious to one ordinary skilled in the art to modify the surface characteristics into hydrophilic or hydrophobic by adding peptides, proteins, polynucleic acids, polyesters, polyureas, polyimides, and the like, to have better affinity for biological molecules. (Col. 14, line 17-25) However, no feature of "photorecognizable coding pattern comprising a hole not penetrating through the entire of said substrate" is taught by Cattell. Dames et al. teach a micro-label design to identify analyte of interest in a solution. Dames et al. teach using a photorecognizable coding pattern on a substrates, i.e. bar code formed by a series of holes on the metal layer. (See page 3, line 26-29) The device taught by Dames et al. provides a low-cost, fast and convenient manner for identifying purposes through flow cytometry reader system, or fluorescence/imaging microscopy. (See page 2, line 13-15; page 3, line 6-8; claim 14-19) The placement of Dames' photorecognizable bar code on the substrate device taught by Cattell would result in a series of "hole not penetrating through the entire of said

substrate". Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided either the device of Cattell with the photorecognizable bar code as taught by Dames et al. for low-cost and convenient identifying analyte of interest in a test sample.

7. Claims 7-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cattell.

Cattell reference has been discussed with respect to the non-specific shapes requirement on the substrate. (Col. 7, line 45-46) However, Cattell reference is silent in specifying the dimensions on the substrates. Nevertheless, it has been held that a change in size is generally recognized as being within the level of ordinary skill in the art. In re Rose, 105 USPQ 237 (CCPA 1955) Furthermore, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided Cattell with alternative size options for the substrates since such manipulations for optimum or workable ranges only involves routine skilled in the art.

8. Claims 12-14, 30 and 93 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cattell in view of Zhou et al. (WO 0054882)

Cattell reference has been discussed before but fails to specifically teach using aluminum, magnetic, nickel or CoTaZr alloy. Zhou et al. teach using external active forces, such as magnetic manipulation over biochips, for detection of biomolecules with the advantages of microfabrication and microelectronic technologies. (page 5, last paragraph and second paragraph; page 6, first paragraph;) Zhou et al. teach using aluminum as the conductive layers beneath an insulating non-metal layers, and method of obtaining a nickel alloy for the biochip. (page 35, first paragraph; page 29, first paragraph) Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the method of Cattell with the metal layers or alloy as taught by Zhou et al,

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since using the active biochips, e.g. external magnetic forces, providing advantages over the passive biochips in microfabrication and microelectronic technologies.

***Response to Applicant's Arguments***

9. Applicant amends claim 1 by incorporating limitation from claim 94 in compliance with the suggestion of examiner's previous Office Action dated on 9/24/2003. The amendment has been considered but nevertheless an established *prima facie* obviousness still renders the instant application not patentable as discussed in this Office Action.

***Conclusion***

10. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacob Cheu whose telephone number is 571-282-0814. The examiner can normally be reached on 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jacob Cheu  
Examiner

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*03/19/04*